Primary Evaluator Yan Donovan, Chemist, RRB4/HED Date: 07/3/06

Approved by Susan Hummel, Senior Scientist, RRB4/HED Date: 07/3/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/12/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

45542401 Vincent, T. (1998) Propiconazole--Magnitude of the Residue in or on Strawberries: Final Report: Lab Project Number: ABR-98066: 48-96: 110S44. Unpublished study prepared by Novartis Crop Protection, Inc. 113 p.

EXECUTIVE SUMMARY:

In 8 field trials conducted throughout the U.S. in 1996, propiconazole (3.6 lb/gal) was applied to strawberries as four broadcast foliar applications during fruit development at 0.11 lb ai/A/application at retreatment intervals (RTIs) of 6-8 days, for a total of 0.44 lb ai/A/season. All applications were made using ground equipment at volumes of 50-100 gal/A, and no adjuvants were used. Single control and duplicate treated samples of strawberries were harvested from each site on the same day as the final application (0 DAT) and at 3 or 8 DAT at two sites. Samples were stored frozen from collection to analysis for up to 18 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on strawberries were determined using an adequate GC/ECD method (Method AG-45B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported. The concurrent recovery of propiconazole averaged 77 ± 8% from control samples fortified at 0.05 or 0.50 ppm. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be established at parent only, there fore, tolerances will not under represent the real residue levels.

Following the last of four foliar applications totaling 0.44 lb ai/A, total uncorrected propiconazole residues were 0.07-0.69 ppm in/on 16 samples of strawberries harvested on the

day of the final application (0 DAT). Average residues were 0.35 ppm and the highest average field trial (HAFT) residues were 0.60 ppm. Data from both residue decline tests indicated that residues declined on strawberries at longer post-treatment intervals.

The number of trials and the geographic representation of the trials are adequate. These data will support the use of propiconazole (EC) on strawberries as up four broadcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season, with a 0-day PHI.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in these studies, the strawberry field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing a tolerance and the use of propiconazole on strawberry. The current submission includes residue data supporting the use on strawberry of propiconazole, formulated as a 3.6 lb/gal EC.

TABLE A.1. Nomenclature of Propiconazole

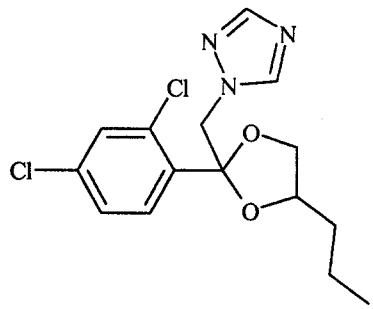
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Strawberries were grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site, along with data on soil characteristics. At each test site, propiconazole (EC) was applied as four broadcast foliar applications using ground equipment (Table B.1.2). No adjuvants were included in the spray mixtures.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Fresno, CA 1996	Sandy loam	0.7	5.7	7.25
Hillsborough, FL 1996	Sand	2.3	6.8	5.99
Wayne, NC 1996	Loamy sand	0.6	5.0	1.79
Monterey, CA 1996	Sandy loam	2.2	7.0	7.63
San Bernardino, CA 1996	Sandy loam	1.8	5.2	7.35
Washington, OR 1996	Silt loam	2.9	5.2	14.67
Ottawa, MI 1996	Loamy sand	2.7	6.3	7.11
Wayne, NY 1996	Loamy Sand	2.5	6.4	4.83

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.

TABLE B.1.2. Study Use Pattern on Strawberry.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Fresno, CA 1996 02-FR-014-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	50	0.11	7, 7, 7	0.44
Hillsborough, FL 1996 07-FR-001-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	85	0.11	7, 7, 8	0.44
Wayne, NC 1996 0S-FR-601-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	50	0.11	7, 7, 7	0.44
Monterey, CA 1996 0W-FR-502-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	100	0.11	7, 7, 7	0.44
San Bernardino, CA 1996 0W-FR-503-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	75	0.11	6, 8, 6	0.44
Washington, OR 1996 0W-FR-610-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	80	0.11	7, 7, 7	0.44
Ottawa, MI 1996 NE-FR-710-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	51-52	0.11	7, 7, 8	0.44
Wayne, NY 1996 NE-FR-817-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	50	0.11	7, 7, 7	0.44

[1] All applications were made using ground equipment, and no adjuvants were used.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Strawberry		
	Submitted	Requested	
		Canada	U.S.
1	1	---	1
2	1	---	1
3	1	---	1
4	---	---	---
5	1	---	1
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	3	---	3
11	---	---	---
12	1	---	1
Total	8	NA	8

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of strawberries (2-3 lb/sample) were harvested from each site at 0 DAT, and additional treated samples were harvested at 3 or 8 DAT from two sites to examine residue decline. Samples were frozen shortly after harvest and shipped by freezer truck to Novartis Crop Protection (Greensboro, NC), where samples were prepared for analysis and stored at -20 °C. Samples were later shipped frozen on dry ice by overnight courier to the

analytical laboratory, EPL-Bio Analytical Services (Harristown, IL), where samples were stored frozen until analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and the methylated DCBA is analyzed by GC/ECD using external standards. Residues are expressed in propiconazole equivalents. The validated method LOQ is 0.05 ppm for residues, the LOD was not reported.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the tolerance expression will be parent only, there fore, tolerances will not under represent the real residue levels.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of strawberries fortified with propiconazole at 0.05 and 0.50 ppm.

C. RESULTS AND DISCUSSION

In 8 field trials conducted during 1996 in Regions 1, 2, 3, 5, 10 (3 tests) and 12, propiconazole (EC) was applied to strawberries during fruit development as four broadcast foliar applications at 0.11 lb ai/A/application, at RTIs of 6-8 days, for a total of 0.44 lb ai/A/season. All applications were made using ground equipment at volumes of 50-100 gal/A, and no adjuvants were included in the spray mixtures. Single control and duplicate treated samples of strawberries were harvested from each site at 0 DAT, and samples were also collected at 3 or 8 DAT from two test sites to examine residue decline.

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on strawberries was validated in conjunction with the analysis of field trial samples. The recovery

of propiconazole averaged 77 ± 8% from control samples fortified at 0.05 or 0.50 ppm (Table C.1). Apparent residues of propiconazole were <LOQ in/on 8 control samples and just above the LOQ (0.060 ppm) in/on 2 control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD is 0.02 ppm. Adequate sample calculations and example chromatograms were provided.

Strawberry samples were stored frozen for up to 18 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the fortified residues of propiconazole and its metabolites are stable for up to 36 months at -20°C in peaches (DP Barcode D279300, Y. Donovan, 8/18/05). These data will support the storage intervals and conditions for the current field trials.

Following the last of four foliar applications totaling 0.44 lb ai/A, total uncorrected propiconazole residues were 0.07-0.69 ppm in/on 16 samples of strawberries harvested at 0 DAT (Table C.3). Average residues were 0.35 ppm and HAFT residues were 0.60 ppm (Table C.4). In the two residue decline tests, average residues declined from 0.16 ppm at 0 DAT to 0.12 ppm at 3 DAT in one test and from 0.19 ppm at 0 DAT to 0.11 ppm at 8 DAT in the other test.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Strawberry.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Strawberry	0.05	4	67, 76, 93, 83	77 ± 8
		0.50	6	74, 83, 80, 71, 69, 71	

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Strawberry	-20	12-18	36

[1] From harvest to extraction for analysis. Extracts were stored for 1-3 days prior to analysis.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data on Strawberry from Field Trials with Propiconazole (EC).							
Trial ID (County, State; Year)	Zone	Variety	End-use Product	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Fresno, CA 1996 02-FR-014-96	10	Camarosa	3.6 lb/gal EC	0.44	Fruit	0	0.16, 0.15
						3	0.10, 0.13
Hillsborough, FL 1996 07-FR-001-96	3	Oso Grande	3.6 lb/gal EC	0.44	Fruit	0	0.41, 0.60
Wayne, NC 1996 0S-FR-601-96	2	Chandler	3.6 lb/gal EC	0.44	Fruit	0	0.38, 0.69
Monterey, CA 1996 0W-FR-502-96	10	776	3.6 lb/gal EC	0.44	Fruit	0	0.58, 0.61
San Bernardino, CA 1996 0W-FR-503-96	10	Chandler	3.6 lb/gal EC	0.44	Fruit	0	0.26, 0.24
Washington, OR 1996 0W-FR-610-96	12	Totem	3.6 lb/gal EC	0.44	Fruit	0	0.07, 0.22
Ottawa, MI 1996 NE-FR-710-96	5	Kent	3.6 lb/gal EC	0.44	Fruit	0	0.19, 0.19
						8	0.11, 0.11
Wayne, NY 1996 NE-FR-817-96	1	Tribute	3.6 lb/gal EC	0.44	Fruit	0	0.38, 0.39

[1] Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on strawberry, and the LOD is 0.02 ppm.

TABLE C.4. Summary of Residue Data from Strawberry Field Trials with Propiconazole (EC).										
Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Strawberry	0.44	3.6 lb/gal EC	0	16	0.07	0.69	0.60	0.32	0.35	0.19

[1] The LOQ is 0.05 ppm. Residue data are not corrected for procedural recoveries.
[2] HAFT = Highest Average Field Trial.
[3] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The strawberry field trial data are adequate and will support the use of propiconazole (EC) on strawberries as up four broadcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season, with a 0-day PHI.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

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